AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for treating amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or suppressing the progression thereof, which comprises administering to a patient in need thereof as an active ingredient a pyrazolone derivative compound represented by the following formula (I), or a physiologically acceptable salt thereof, or a hydrate thereof or a solvate thereof:

[Chem. 1]

$$R^{2} \xrightarrow{\begin{array}{c} R^{1} \\ N \\ N \\ R^{3} \end{array}}$$

wherein R^1 represents a hydrogen atom, aryl, C_{1-5} alkyl, or C_{3-6} (total carbon number) alkoxycarbonylalkyl, R^2 represents a hydrogen atom, aryloxy, arylthio, C_{1-5} alkyl or C_{1-3} hydroxyalkyl, or R^1 and R^2 are combined with each other to represent C_{3-5} alkylene group, and R^3 represents a hydrogen atom, C_{1-5} alkyl, C_{5-7} cycloalkyl, C_{1-3} hydroxyalkyl, benzyl, naphthyl or phenyl, or phenyl substituted with the same or different 1 to 3 substituents selected from the group consisting of C_{1-5} alkoxy, C_{1-3} hydroxyalkyl, C_{2-5} (total carbon number) alkoxycarbonyl, C_{1-3} alkylthio, C_{1-4} alkylamino, C_{2-8} (total carbon number) dialkylamino, halogen atom, trifluoromethyl, carboxyl, cyano, hydroxyl group, nitro, amino and acetamide, under the condition that a drug holiday period of 1 day or more is provided once, twice or more during the period for treating the disease or suppressing the progression of the disease.

- **2.** (Currently amended) The method of claim 1, wherein the pyrazolone derivative compound is 3-methyl-1-phenyl-2-pyrazoline-5-on.
- **3.** (**Previously presented**) The method of claim 1, wherein the drug holiday period is provided after a drug administration period of about 7 to 14 days.

YOSHINO et al. Serial No. 10/588,778 Attorney Docket No. 2006 1312A

January 21, 2010

4. (Previously presented) The method of claim 1, wherein a second or subsequent drug

administration period is about 5 to 14 days.

5. (Previously presented) The method of claim 1, wherein the drug holiday period is about

14 to 16 days.

6. (Previously presented) The method of claim 1, wherein the drug administration period and

the drug holiday period are each 14 days.

7. (Previously presented) The method of claim 1, wherein a course consisting of an initial

drug administration period of 14 days and a drug holiday period of 14 days is provided, followed

by repetitions of the following combination of periods:

drug administration period: 5 days per week for 2 weeks; and

drug holiday period: 14 days.

8. (Currently amended) The method of claim 1, wherein the daily dose contains about 15 to

240 mg of a pyrazolone derivative compound as an active ingredient, or about 15 to 240 mg of a

pyrazolone derivative-compound contained in a pharmaceutically acceptable salt of a pyrazolone

derivative compound or a hydrate or solvate of a pyrazolone derivative compound or a

pharmaceutically acceptable salt thereof as an active ingredient.

9. (Currently amended) The method of claim 1, wherein the daily dose contains about 60

mg of a pyrazolone derivative compound as an active ingredient, or about 60 mg of a pyrazolone

derivative compound contained in a pharmaceutically acceptable salt of a pyrazolone derivative

compound or a hydrate or solvate of a pyrazolone derivative compound or a pharmaceutically

acceptable salt thereof as an active ingredient.

10. (Previously presented) The method of claim 1, wherein the administration is carried out

once daily.

3

YOSHINO et al. Serial No. 10/588,778 Attorney Docket No. 2006_1312A

January 21, 2010

11. (Previously presented) The method of claim 1, wherein the administration is a continuous

administration.

12. (Previously presented) The method of claim 11, wherein the continuous administration is

intravenous infusion administration.

13. (Currently amended) The method of claim 12, wherein the administration rate in the

intravenous infusion administration is about 0.5 to 1 mg/minute with respect to a pyrazolone

derivative compound as an active ingredient or a pyrazolone derivative compound contained in

an active ingredient.

14. (Currently amended) The method of claim 11, wherein the continuous administration is

an administration form that is substantially equivalent to the intravenous infusion administration

wherein the amount of a pyrazolone derivative compound as an active ingredient or a pyrazolone

derivative compound contained in an active ingredient administered per minute is about 0.5 to 1

mg.

15. (Currently amended) The method of claim 1, wherein the symptoms caused by

amyotrophic lateral sclerosis are decreased respiratory function, voice and speech disorders,

dysphagia, or upper and lower extremity motor disorders.

16. (Currently amended) The method of claim 1, wherein the treatment of amyotrophic

lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or the suppression of

the progression thereof is a suppression of decrease in respiratory function in amyotrophic lateral

sclerosis.

17-32. (Cancelled)

4